

Food and Drug Administration, HHS

§ 558.55

Drug sponsor	Type A article	Species	Use levels	Indications for use
Fermenta Animal Health Co. ....	Bacitracin methylene disalicylate.	Chicken turkeys, swine, and cattle.	Sec. 558.76 .....	Sec. 558.76.

(2) [Reserved]

[51 FR 8811, Mar. 14, 1986; 51 FR 11014, Apr. 1, 1986, as amended at 51 FR 28547, Aug. 8, 1986; 53 FR 20843, June 7, 1988; 54 FR 37098, Sept. 7, 1989; 54 FR 51386, Dec. 15, 1989; 55 FR 8460, 8462, Mar. 8, 1990; 56 FR 41912, Aug. 23, 1991; 56 FR 64702, Dec. 12, 1991; 57 FR 6476, Feb. 25, 1992; 57 FR 8577, Mar. 11, 1992; 57 FR 14639, Apr. 22, 1992; 58 FR 17515, Apr. 5, 1993; 58 FR 30119, May 26, 1993; 61 FR 51589, Oct. 3, 1996; 64 FR 992, Jan. 7, 1999; 64 FR 37673, July 13, 1999; 71 FR 16221, Mar. 31, 2006; 75 FR 16002, Mar. 31, 2010]

**Subpart B—Specific New Animal Drugs for Use in Animal Feeds**

**§ 558.55 Amprolium.**

(a) *Approvals.* Type A medicated articles: 25 percent to No. 016592 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(b) *Special considerations.* Do not use in Type B or Type C medicated feeds containing bentonite.

(c) *Related tolerances.* See § 556.50 of this chapter.

(d) *Conditions of use—(1) Cattle.* It is used as follows:

Amprolium in Grams per Ton	Indications for Use	Limitations	Sponsor
(i) 113.5 to 11,350; to provide 5 milligrams (mg) per kilogram of body weight per day.	Calves: As an aid in the prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zurnii</i> .	Top-dress on or mix in the daily ration. Feed for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; as sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.	050604
(ii) 113.5 to 11,350; to provide 10 mg per kilogram of body weight per day.	Calves: As an aid in the treatment of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zurnii</i> .	Top-dress on or mix in the daily ration. Feed for 5 days; as sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. For a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined.	050604

(i) *Amount.* 227 milligrams per 100 pounds (5 milligrams per kilogram) body weight per day.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(b) *Limitations.* Administer from a Type B feed containing from 0.05 to 1.25 percent amprolium with the usual amount of feed consumed in 1 day; feed for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; with-

draw 24 hours before slaughter; as sole source of amprolium. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) *Amount.* 454 milligrams per 100 pounds (10 milligrams per kilogram) body weight per day.

(a) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(b) *Limitations.* Administer from a Type B feed containing from 0.05 to 1.25 percent amprolium with the usual amount of feed consumed in 1 day; feed for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug

should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter; as sole source of amprolium. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Chickens and turkeys.* It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5 (0.004% to 0.0125%).		Replacement chickens; development of active immunity to coccidiosis.	Feed as follows—	
Growing conditions		Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
Severe exposure to coccidiosis		Amprolium grams per ton 113.5 (0.0125%)	Amprolium grams per ton 72.6–113.5 (0.008%–0.0125%)	Amprolium grams per ton 36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis		72.6–113.5 (0.008%–0.0125%)	54.5–113.5 (0.006%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Slight exposure to coccidiosis		36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)

  

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5 (0.004% to 0.0125%).	Arsanilic acid 90 (0.01%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic; feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease during periods of stress. 2. Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).  Feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	

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Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bacitracin 100 to 200.	Replacement chickens; development of active immunity to coccidiosis; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).	As bacitracin methylene disalicylate or bacitracin zinc. Feed according to subtable in item (i).	
	Bacitracin methylene disalicylate 4 to 50.	Replacement chickens; development of active immunity to coccidiosis, increased rate of weight gain, and improved feed efficiency.	Feed according to subtable in item (i); bacitracin methylene disalicylate as provided by 046573 in §510.600(c) of this chapter..	046573
	Bacitracin methylene disalicylate 50 plus roxarsone 22.7 to 45.4.	Replacement chickens; development of active immunity to coccidiosis; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin; increased rate of weight gain, improved feed efficiency, and improved pigmentation..	Feed according to subtable in entry (i); bacitracin methylene disalicylate and roxarsone as provided by 046573 in §510.600(c) of this chapter..	046573
	Chlortetracycline 100 to 200.	Chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Erythromycin 4.6 to 18.5.	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.	As erythromycin thiocyanate. Feed according to subtable in item (i).	
	Erythromycin 92.5 .....	1. Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of infectious coryza. 2. Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress.	Feed for 7 to 14 d; withdraw 24 h before slaughter. Feed according to subtable in item (i). Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter. Feed according to subtable in item (i).	
	Erythromycin 185 .....	Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter. Feed according to subtable in item (i).	
	Hygromycin B 8 to 12	Replacement chickens; development of active immunity to coccidiosis; control of infestation of large round worms ( <i>Ascaris galli</i> ), cecal worms ( <i>Heterakis gallinae</i> ), and capillary worms ( <i>Capillaria obsignata</i> ).	Feed according to subtable in item (i).	
	Penicillin 2.4 to 50 .....	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency.	As procaine penicillin. Feed according to subtable in item (i).	

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(ii) 72.6 to 113.5 (0.008% to 0.0125%).	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion, and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic. Feed according to subtable in item (i).	
	.....	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> only.	Feed according to subtable in item (i).	
	Arsanilic acid 90 (0.01%).	.....do .....	.....do.	
	Bacitracin 100 to 200	Broiler chickens; prevention of coccidiosis caused by <i>E. tenella</i> only; treatment of chronic respiratory disease (air-sac infection) and blue comb (nonspecific infectious enteritis).	As bacitracin methylene disacylate, or zinc bacitracin.	
	Chlortetracycline 100 to 200.	Chickens; prevention of coccidiosis caused by <i>E. tenella</i> only; control of infectious synovitis caused by <i>M. synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens; prevention of coccidiosis caused by <i>E. tenella</i> only; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Hygromycin B 8 to 12	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> only; control of infestation of large round worms ( <i>Heterakis gallinae</i> ), and capillary worms ( <i>Capillaria obsignata</i> ).	Feed according to subtable in item (i).	
(iii) 113.5 (0.0125%) ...	Penicillin 2.4 to 50 .....	Broiler chickens; prevention of coccidiosis caused by <i>E. tenella</i> only; growth promotion and feed efficiency.	As procaine penicillin.	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Broiler chickens; prevention of coccidiosis caused by <i>E. tenella</i> only; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	
	.....	1. Laying chickens; prevention of coccidiosis. 2. Laying chickens; treatment of coccidiosis.	.	
	Bambermycins 1 to 3 plus roxarsone 22.8 to 34.1 (0.0025% to 0.00375%).	Broiler chickens; as an aid in the prevention of coccidiosis; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	For moderate outbreaks of coccidiosis; administer for 2 weeks. Feed continuously as the sole ration; as sole source of amprolium and organic arsenic; roxarsone as provided by No. 053501 in § 510.600(c) of this chapter, bambermycins by No. 016592; withdraw 5 d before slaughter.	
(iv) 113.5 to 227 (0.0125% to 0.025%).	Bambermycins 1 to 4	Growing turkeys; prevention of coccidiosis; increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole source of amprolium; bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
	.....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis. 2. Turkeys; prevention of coccidiosis.		

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Arsanilic acid 90 (0.01%).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation. 2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	.....do.  .....do.	
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of chronic respiratory disease during periods of stress. 2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 5 d before slaughter; as sole source of organic arsenic.  Feed for 7 to 14 d; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improved pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.	
	Bacitracin 4 to 50 .....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency. 2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.	As bacitracin methylene disalicylate or bacitracin zinc.  .....do.	
	Bacitracin 100 to 200	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis). 2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis).	.....do.  As bacitracin zinc.	1012769

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bacitracin 100 to 500	Turkeys; prevention of coccidiosis; treatment of infectious sinusitis, blue comb (mud fever).	As bacitracin zinc.	016592
	Bacitracin plus penicillin 100 to 500 (of combination).	.....do .....	Feed contains 50% to 75% of bacitracin but not more than 125 g penicillin; as procaine penicillin; as bacitracin zinc.	
	Carbarsone 227 to 340.5.	Turkeys; aid in prevention of coccidiosis ( <i>Eimeria adenoeides</i> , <i>E. meleagrimitis</i> , and <i>E. gallopavonis</i> ) and blackhead.	Feed continuously 2 weeks before coccidiosis and blackhead are expected and continue as long as prevention is needed; withdraw 5 days before slaughter; use as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; carbarsone by 046573 in §510.600(c) of this chapter.	
	Chlortetracycline 100 to 200.	Chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by <i>M. synoviae</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Chlortetracycline 200 to 400.	Chickens where immunity to coccidiosis is not desired; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 d.	
	Erythromycin 4.6 to 18.5.	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency.	As erythromycin thiocyanate.	
	Erythromycin 92.5 .....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of chronic respiratory disease during periods of stress. 2. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention of infectious coryza.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter.  Feed for 7 to 14 d; withdraw 24 h before slaughter.	
	Erythromycin 185 .....	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.	Feed for 5 to 8 d, do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter.	
	Hygromycin B 8 to 12	Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infestation of large round worms ( <i>Heterakis gallinae</i> ) and capillary worms ( <i>Capillaria obsignata</i> ).	Feed according to subtable in item (i).	

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Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Penicillin 2.4 to 50 .....	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency. 2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency.	As procaine penicillin. .....do.	
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	1. Broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation. 2. Turkeys; prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic. .....do.	
(v) 227 (0.025%) .....	.....	Laying chickens; treatment of coccidiosis.	For severe outbreaks of coccidiosis; administer for 2 weeks.	

<sup>1</sup> Bacitracin zinc in § 510.600(c) of this chapter.

(3) *Pheasants*. It is used as follows:

(i) *Amount*. 0.0175 percent (159 grams per ton).

(ii) *Indications for use*. For the prevention of coccidiosis in growing pheasants caused by *Eimeria colchici*, *E. duodenalis*, and *E. phasianii*.

(iii) *Limitations*. Feed continuously as sole ration. Use as sole source of amprolium. Fertility, hatchability, and other reproductive data are not available on amprolium in breeding pheasants. Do not use in feeds containing bentonite.

[41 FR 10985, Mar. 15, 1976]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.55, see the List of CFR Sections Affected, which appears in the

Finding Aids section of the printed volume and at [www.fdsys.gov](http://www.fdsys.gov).

**§ 558.58 Amprolium and ethopabate.**

(a) *Specifications*. Type A medicated articles containing:

(1) 25 percent amprolium and 8 percent ethopabate or 5 percent amprolium and 1.6 percent ethopabate;

(2) 25 percent amprolium and 0.8 percent ethopabate or 5 percent amprolium and 0.16 percent ethopabate.

(b) *Approvals*. See No. 016592 in § 510.600(c) of this chapter.

(c) *Special considerations*. Do not use in Type B or Type C medicated feeds containing bentonite.

(d) *Related tolerances*. See §§ 556.50 and 556.260 of this chapter.

(e) *Conditions of use*. (1) It is used for chickens as follows:

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) Amprolium 113.5 (0.0125 pct) and ethopabate 3.6 (0.0004 pct).	.....	Broiler chickens as an aid in the prevention of coccidiosis.	Not for laying hens; as sole source of amprolium.	016592